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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,433	10/16/2001	Andrew D. Murdin	032931-0256	2926

7590 12/12/2003

Michele M Simkin
Foley & Lardner
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	15

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,433	MURDIN ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-87* is/are pending in the application.

4a) Of the above claim(s) *63-78, 79 (e) 80-82, 84 and 85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-62,79,83,86 and 87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *44-87* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. Applicant's amendment filed on 9/11/03 (paper # 14) is acknowledged. Claims 44-47, 50-52, 56, 59, 61-64, 70, 71, 74 & 76-84 have been amended. New claims 86-87 have been added. Claims 44-87 are pending in the application.

2. Upon further review of the application, the examiner has included newly amended claims 44, 46-50 and newly added claims 86-87 drawn to nucleic acid, to the elected invention, Therefore, claims 44-62, 79, 83 & 86-87, drawn to DNA are under prosecution.

3. Claims 63-78, 79 (e) 80-82, 84 and 85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

4. The examiner acknowledges the various amendments made to the specification in response to the previous Office action.

5. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

6. In view of the amendments to the claims, the rejection under 35 U.S.C. 101 is withdrawn

7. In view of the abandonment of the pending application 09/892,851, the rejection under the judicially created doctrine of obviousness-type double patenting is withdrawn. Applicant is advised to send a copy of the abandonment of application 09/892,851, so that the record is complete.

8. In view of the submission of complete information for making plasmid pCA1764 and teaching of SEQ.ID.NO: 1 which encodes SEQ.ID.NO: 2 has been cloned and expressed in plasmid pCA1764, the rejection of claim 83 under 35 U.S.C. 112, first paragraph is withdrawn.

9. In view of the amendments to the claims, the rejection under 35 U.S.C. 112, second paragraph is withdrawn.

10. In view of the amendments to the claims, the rejections under 35 U.S.C. 112, first paragraph are withdrawn for recitation of %identity.

New Rejections based on the amendment

11. 35 U.S.C. 101 reads as Follows

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

12. Claims 44 and 47-50 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The product, a nucleic acid as claimed, has the same characteristics as that found in nature. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics of applicant's product from the product, as it exists in nature. It is further suggested that such limitation include the terminology " purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's product nucleic acid is "free of" relative to the natural source. (see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

13. Claims 44, 46-57, 59-60, 83, 86, and 87 are rejected under 35 U.5.C. 112, first paragraph (written description) as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification broadly describes as part of the invention isolated polynucleotide, SEQ.ID.NO: 1 and the encoding polypeptide, SEQ ID NO: 2. Applicants broadly describe the

invention as (a) a nucleotide sequence encoding an immunogenic fragment comprising at least 12 or 20 consecutive amino acids, fusion protein comprising said fragment, vaccine or pharmaceutical composition comprising at least 12 or 20 amino acids and an isolated nucleic acid comprising 38 or 60 consecutive nucleotides, Applicants broadly describe the invention as embracing any nucleic acid molecule substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides found in the encoding or reference sequence by use of language in which a specified percent of amino acids can be changed in the polypeptide. As depending from these are the vectors, host cells, vaccines, and pharmaceutical compositions. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polynucleotide sequence comprising the nucleic acid sequence SEQ ID NO: 1 which corresponds to the polynucleic acid sequence encoding the Chlamydia pneumoniae protein which comprises SEQ ID N0: 2. Thus, an isolated polynucleotide sequence comprising the nucleic acid sequence, SEQ ID NO: 1 and the protein, SEQ.ID.NO: 2, that is encoded by said SEQ.ID.NO: 1 meet the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below:

The specification fails to teach a nucleotide sequence encoding an immunogenic fragment comprising at least 12 or 20 consecutive amino acids (examiner is considering them as variants), fusion protein comprising said fragment, vaccine or pharmaceutical composition

comprising at least 12 or 20 amino acids and an isolated nucleic acid comprising 38 or 60 consecutive nucleotides (examiner is considering them as variants). There is no written description support for said nucleic acid variants.

Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicant's invention as a protein that is uncharacterized by this specification and is not belong to any known family of proteins. The protein has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence, which encodes it. With the exception of an isolated polynucleotide comprising the nucleic acid sequence SEQ ID NO: 1 and an isolated polynucleotide comprising the nucleotide sequence encoding SEQ ID NO: 2, fragments thereof and associated, vectors, vaccines, fusion proteins etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides. Adequate written description requires more than a mere statement that it is part of the invention See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Applicant's arguments filed on 9/11/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the specification on pages 19 and 12 fully describe the claimed immunogenic fragments. The examiner reviewed the cited pages and found no specific support for the claimed invention. Further applicant argues that the present invention is not related to Eli Lilly and Amgen and not claiming a chemical compound by name and hoped for function as in

Eli Lilly, or a mere elucidation of a research plan to obtain a chemical compound described by name only as in Amgen. Applicant further states that the specification clearly describes the claimed fragments and variants.

The examiner disagrees with the applicant because applicant indeed is claiming a compound product such as immunogenic fragment comprising 12 amino acids or 50 amino acids SEQ.ID.NO: 1 by name/numbers without a function like Eli Lilly. Similarly, applicant is claiming a compound fragments like Amgen in describing general techniques in the art without a specific property.

14. Claims 44, 46-57, 59-60, 83, 86, and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleic acid sequence as set forth in SEQ.ID.NO: 1 or an isolated nucleic acid which encodes the polypeptide SEQ.ID.NO: 2, a vaccine or a pharmaceutical composition comprising said nucleic acid does not reasonably provide enablement for a nucleotide sequence encoding an immunogenic fragment comprising at least 12 or 20 consecutive amino acids(examiner is considering them as variants), , fusion protein comprising said fragment, vaccine or pharmaceutical composition comprising at least 12 or 20 amino acids and an isolated nucleic acid comprising 38 or 60 consecutive nucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Scope of enablement requires that the specification teach those in the art how to make and use the invention commensurate with the scope of the claimed invention without undue experimentation and includes an analysis of: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance

present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification is not enabling for the claimed invention because the specification does not provide sufficient guidance as to how an artisan would have made all the polynucleotide sequences, vectors, and host cells expressing the polynucleotide sequences as claimed above and would have used those without undue experimentation because the state of the prior art in the field of C.pneumoniae ATP/ADP translocase coding gene is not known. Further, the amino acid sequence encoding the C.pneumoniae ATP/ADP translocase-coding gene with respect to virulence and/or protection is also not known.

It is noted that the specification, in pages 48-51 provides description of an expression vector containing the C.pneumoniae gene, i.e. pCA1764 and immunization of mice to achieve protection against an intranasal challenge of C.pneumoniae. However, the specification fails to teach a nucleotide sequence encoding an immunogenic fragment comprising at least 12 or 20 consecutive amino acids (examiner is considering them as variants), fusion protein comprising said fragment, vaccine or pharmaceutical composition comprising at least 12 or 20 amino acids and an isolated nucleic acid comprising 38 or 60 consecutive nucleotides. The specification does not provide how would an artisan have made said nucleic acid molecule. Even if one had to assume that using various molecular biology techniques described in the specification in pages 18-21, an artisan would have been able to make these polynucleotides, would all the polypeptides encoded by the isolated polynucleotides have had any specific function with respect to virulence and/or protection against C.pneumoniae is questionable. It is concluded that the specification as filed is not enabling for the claimed invention as filed and an artisan would not have been able to practice the invention without undue experimentation. Therefore, limitation of the scope of the invention to an isolated nucleic acid molecule comprising the

nucleic acid sequence SEQ.ID.NO: 1, a vaccine or pharmaceutical composition comprising said nucleic acid is proper.

Applicant's arguments filed on 9/11/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the specification is fully enabled for the claimed variants or fragments without undue experimentation one skilled in the art can make and use the claimed invention and gives the In re wands analysis. Applicant cites several general protocols obtained from Web sites and provides case laws to support the claimed fragments or variants are fully enabled and the examiner should withdrawn the scope of enablement rejection.

The examiner has reviewed the Web sites and also other available art regarding protein chemistry and disagrees with the applicant because

The state of the prior art indicates that protein chemistry is probably one of the most unpredictable areas of biotechnology and is highly complex. As taught by the prior art (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6), the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted a priori and must be determined empirically on a case by case basis. The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology,

8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of a single amino acid residue may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67) teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which products proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of

2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 44-62, 79 & 86-87, are rejected under 35 U.S.C. 102(a) as being anticipated by Kalman et al. (Accession number AE001619, 'Submitted 12/1/98' & 'Nat. Genet. 1999, 21(4): 385-389, reference A 58 on PTOL-1449).

Claims are drawn to an isolated nucleic acid, a vaccine or a pharmaceutical composition comprising the nucleic acid sequence as set forth in SEQ.ID.NO: 1 or an isolated nucleic acid which encodes a polypeptide SEQ.ID.NO: 2, an isolated nucleic acid comprising a nucleotide sequence encoding an immunogenic fragment comprising at least 12 or 20 consecutive amino acids, fusion protein comprising said fragment, vaccine or pharmaceutical composition comprising at least 12 or 20 amino acids and an isolated nucleic acid comprising 38 or 60 consecutive nucleotides. a probe of 5 to 100 nucleotides and a primer of 10-40 nucleotides of nucleic acid molecule SEQ.ID.NO: 1.

Kalman et al. disclose nucleotide sequences SEQ ID NO: 1 (see the sequence alignment for a nucleotide sequence 100% identical including 5-100 and 10-40 nucleotides). Therefore, the prior art meets the limitations of claims. Kalman et al also disclosed that DNA was isolated and cloned in to M13 (see page 388) that encodes a polypeptide. Therefore, the prior art meets the limitations of a vector (M13) and a nucleic acid sequence that encodes a polypeptide (see the sequence alignment for a nucleotide sequence). The terms "vaccine" and "pharmaceutical composition" are intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed inventions from the prior art. If the prior art structure is capable of performing the intended use, then it meets the

claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of Kalman et al.

It is acknowledged that weight is given to every term in claims 51 and 52 This is why the instant claims 51and 52 drawn to vaccines and pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid and formulations thereof as claimed.

Applicant's arguments filed on 9/11/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the examiner failed to show where Kalman et al stated that these proteins produced recombinantly, Kalman et al does not disclose or suggest expressing sequences and Kalman does show only entire genome sequence.

The examiner would like to bring applicant's attention to the claims, which do not recite that these proteins are produced recombinantly or expressed as proteins in a construct. Further, Applicant's use of the open-ended term "having " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on any sequence including genomic sequence, which inherently comprises claimed nucleic acid molecules. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art nucleic acid molecule and the claimed nucleic acid molecule are the same. Since the Office does not have the facilities for

examining and comparing applicants' claimed isolated nucleic acid with the nucleic acid sequence of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Vaccine composition or pharmaceutical compositions are considered as intended use of said disclosed nucleic acid molecule.

17. Claims 61-62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60- -- 62).

The claims are drawn to isolated nucleic acid sequences, which are probes and primers having variable lengths (5-100 nucleotides) based on SEQ ID NO: 1 or complements thereof.

Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60-62) each disclose a wide variety of probes, primers and linkers of over 10 nucleotides in length. Thus the disclosed random primers, probes and linkers anticipated the instant claims. The primers and linkers have been applied as relevant to the restriction map provided for SEQ ID NO: 1.

Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 product Catalog, page 66), disclose kits containing isolated packaged random 6-mer primers and random 9-mer primers. The random primer kits contain all possible 6 mer and 9 mer sequences for priming DNA sequences for labeling. The prior art anticipated the claimed invention.

Applicant states that none of the cited references disclose the elements of the claims because a purified probe or a primer have not explicitly disclose the sequences that can be

compared with the sequences of claims 61-62. Applicant further states, Examiner might have rejected the claims based on inherency.

The examiner has not rejected claims based on inherency but clearly indicated that the random primer kits contain all possible 6 mer and 9 mer sequences for priming DNA sequences for labeling are widely available in the market. For example see Promega Catalogue discloses 8mer GGAATTCC that hybridizes with SEQ.ID.NO; 1 at position approximately between 880-900. Further these probes are isolated and labeled.

18. Claims 44-62, 79 & 86-87 are rejected under 35 U.S.C. 102 (a) as being anticipated by Griffais R (Accession No: AAX91990, WO 9927105, published on 6/3/99).

Claims are discussed supra.

Griffais R discloses a nucleotide sequence that is 99.8% identical to SEQ ID NO: 1 (see the sequence alignment including 5-100 and 10-40 nucleotides). Therefore, the prior art meets the limitations of claims. The terms "Applicant's use of the open-ended term "having " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art nucleic acid and claimed nucleic acid are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed inventions from the prior art. If the prior art structure is capable

of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of Griffais R.

It is acknowledged that weight is given to every term in claims 51 and 52 This is why the instant claims 51and 52 drawn to vaccines and pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid and formulations thereof as claimed. The prior art anticipated the claimed invention.

Applicant's arguments filed on 9/11/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the prior art does not provide or disclose ADP/ATP translocase out of 1296 ORFS, points to nucleic acid at position 895 and 921 out of 1637 nucleic acids, and cites many case laws. The examiner would like to bring applicant's attention to the cited nucleic acid, which encodes a protein, which is 99.5% identical to the claimed invention although it differs at position 895 and 921. (see the sequence alignment). However, Griffais R discloses a nucleotide sequence that is 99.8% identical to SEQ ID NO: 1 (see the sequence alignment including 5-100 and 10-40 nucleotides. Griffais R also discloses all proteins encoded by open reading frames including a nucleotide sequence that encodes SEQ.ID.NO: 2 (see SEQ.ID.NO: 369). Further, Applicant's use of the open-ended term "having " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on any sequence including genomic sequence, which inherently comprises claimed nucleic acid molecules. See In re

Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art nucleic acid molecule and the claimed nucleic acid molecule are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated nucleic acid with the nucleic acid sequence of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Vaccine composition or pharmaceutical compositions are considered as intended use of said disclosed nucleic acid molecule.

19. Claims 44-62, 79& 86-87 are rejected under 35 U.S.C. 102 (e) as being anticipated by Griffais R, U.S.Patent 6, 559,294.

Claims are discussed supra.

(The examiner is viewing the composition claims as intended use of the claimed invention, isolated nucleic acid molecule)

Griffais U.S.Patent 6, 559, 294 discloses a nucleic acid sequence (SEQ.ID.NO: 1, see the sequence alignment) from C. pneumoniae which encodes a polypeptide SEQ.ID.NO: 2, immunogenic fragment comprising at least 10 or 20 amino acids or an isolated nucleic acid molecule comprising 38 or 60 consecutive nucleotides (see the sequence alignment) and is 99.5 % identical to SEQ ID NO: 2. Therefore, the prior art meets the limitations of claimed nucleic acid molecule. SEQ.ID.NO: 369 of Griffais disclose the protein of the claimed invention and is 99.5% identical. The terms "Applicant's use of the open-ended term "having " in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts.. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the

absence of evidence to the contrary the disclosed prior art nucleic acid and claimed nucleic acid are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed inventions from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of Griffais R.

It is acknowledged that weight is given to every term in claims 51 and 52 This is why the instant claims 51and 52 drawn to vaccines and pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid and formulations thereof as claimed. The prior art anticipated the claimed invention.

Status of Claims

20 No claims are allowed.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

MARK NAVARRO
PRIMARY EXAMINER